

Message

From: McNally, Robert [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EFA5514317E34B9895687D73730FDDE9-ROBERT MCNALLY]
Sent: 2/1/2019 10:30:53 PM
To: Miller, Wynne [Miller.Wynne@epa.gov]
CC: Ellis, Frank [Ellis.Frank@epa.gov]; Jones, Russell [Jones.Russell@epa.gov]; Keigwin, Richard [Keigwin.Richard@epa.gov]; Messina, Edward [Messina.Edward@epa.gov]
Subject: Re: Biostimulants - Nancy Beck Request

We will try to go so as soon as we can.

Thanks

Sent from my iPhone

On Feb 1, 2019, at 5:29 PM, Miller, Wynne <Miller.Wynne@epa.gov> wrote:

Hi Bob, Frank and Russ,
Biostimulants came up today on the OCSPP IO morning call. Nancy Beck would like us to finish up our responses to OMB's comments. She realizes that we have comments from USDA and a meeting with DOJ in Feb; however, she would still like us to get back to OMB on their comments. TJ gave his input on the economics portion today so BEAD is done. Not sure if BPPD had anything else to do on the responses but can BPPD tidy these up, send them to Rick early next week so he can review before you send to RCS?
Thx so much,
Wynne

From: Wyatt, TJ

Sent: Friday, February 01, 2019 12:17 PM

To: Chun, Melissa <Chun.Melissa@epa.gov>; Jones, Russell <Jones.Russell@epa.gov>; McNally, Robert <McNally.Robert@epa.gov>; Varco, Joseph <varco.joseph@epa.gov>; Gsell, Alyssa <Gsell.Alyssa@epa.gov>; Kaczmarek, Chris <Kaczmarek.Chris@epa.gov>; Ambrosino, Helene <Ambrosino.Helene@epa.gov>; VanAkkeren, Brett <VanAkkeren.Brett@epa.gov>; Hofmann, Angela <Hofmann.Angela@epa.gov>; Chumble, Prasad <Chumble.Prasad@epa.gov>; Smoot, Cameo <Smoot.Cameo@epa.gov>; Watkins, Stephen <watkins.stephen@epa.gov>; Hoyt, Sarita <Hoyt.Sarita@epa.gov>; Mosby, Jackie <Mosby.Jackie@epa.gov>; Miller, Wynne <Miller.Wynne@epa.gov>

Cc: Kiely, Timothy <Kiely.Timothy@epa.gov>

Subject: RE: FROM OMB: EO 12866 Interagency Review: EPA's Guidance for Plant Biostimulant Products: Label Claims Excluded or Regulated under FIFRA as Plant Regulator Claims (RIN 2070-ZA21) - Interagency Comments

Hi!

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

From: Chun, Melissa

Sent: Tuesday, January 29, 2019 3:23 PM

To: Jones, Russell <Jones.Russell@epa.gov>; McNally, Robert <McNally.Robert@epa.gov>; Varco, Joseph <varco.joseph@epa.gov>; Gsell, Alyssa <Gsell.Alyssa@epa.gov>; Kaczmarek, Chris <Kaczmarek.Chris@epa.gov>; Ambrosino, Helene <Ambrosino.Helene@epa.gov>; VanAkkeren, Brett <VanAkkeren.Brett@epa.gov>; Wyatt, TJ <Wyatt.TJ@epa.gov>; Hofmann, Angela <Hofmann.Angela@epa.gov>; Chumble, Prasad <Chumble.Prasad@epa.gov>; Smoot, Cameo <Smoot.Cameo@epa.gov>; Watkins, Stephen <watkins.stephen@epa.gov>; Hoyt, Sarita <Hoyt.Sarita@epa.gov>; Mosby, Jackie <Mosby.Jackie@epa.gov>; Miller, Wynne <Miller.Wynne@epa.gov>

Subject: FW: FROM OMB: EO 12866 Interagency Review: EPA's Guidance for Plant Biostimulant Products: Label Claims Excluded or Regulated under FIFRA as Plant Regulator Claims (RIN 2070-ZA21) - Interagency Comments

Hi all,

Welcome back.

Here's where we left off on biostimulants:

Ex. 5 Deliberative Process (DP)

Thanks!

-Melissa

From: Jones, Russell

Sent: Wednesday, December 19, 2018 7:32 AM

To: Chun, Melissa <Chun.Melissa@epa.gov>; McNally, Robert <McNally.Robert@epa.gov>; Varco, Joseph <varco.joseph@epa.gov>; Gsell, Alyssa <Gsell.Alyssa@epa.gov>; Kaczmarek, Chris <Kaczmarek.Chris@epa.gov>; Ambrosino, Helene <Ambrosino.Helene@epa.gov>; VanAkkeren, Brett <VanAkkeren.Brett@epa.gov>; Wyatt, TJ <Wyatt.TJ@epa.gov>; Hofmann, Angela <Hofmann.Angela@epa.gov>; Chumble, Prasad <Chumble.Prasad@epa.gov>; Smoot, Cameo <Smoot.Cameo@epa.gov>; Watkins, Stephen <watkins.stephen@epa.gov>; Hoyt, Sarita

<Hoyt.Sarita@epa.gov>; Mosby, Jackie <Mosby.Jackie@epa.gov>; Miller, Wynne
<Miller.Wynne@epa.gov>

Subject: RE: FROM OMB: EO 12866 Interagency Review: EPA's Guidance for Plant Biostimulant Products: Label Claims Excluded or Regulated under FIFRA as Plant Regulator Claims (RIN 2070-ZA21) - Interagency Comments

I am OK with the new language.

Russell S. Jones, Ph.D., Senior Scientist
Chair, Biochemical Classification Committee
Risk Assessment Branch
Biopesticides & Pollution Prevention Division
Office of Pesticide Programs
US Environmental Protection Agency

P: 703-308-5071; F: 703-308-7026
jones.russell@epa.gov

Office Location:
One Potomac Yard
2777 South Crystal Drive Arlington, VA 22202

Mailing Address:
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001
<http://www.epa.gov/pesticides>
<image002.jpg> <image004.jpg>

From: Chun, Melissa

Sent: Tuesday, December 18, 2018 5:39 PM

To: Jones, Russell <Jones.Russell@epa.gov>; McNally, Robert <McNally.Robert@epa.gov>; Varco, Joseph <varco.joseph@epa.gov>; Gsell, Alyssa <Gsell.Alyssa@epa.gov>; Kaczmarek, Chris <Kaczmarek.Chris@epa.gov>; Ambrosino, Helene <Ambrosino.Helene@epa.gov>; VanAkkeren, Brett <VanAkkeren.Brett@epa.gov>; Wyatt, TJ <Wyatt.TJ@epa.gov>; Hofmann, Angela <Hofmann.Angela@epa.gov>; Chumble, Prasad <Chumble.Prasad@epa.gov>; Smoot, Cameo <Smoot.Cameo@epa.gov>; Watkins, Stephen <watkins.stephen@epa.gov>; Hoyt, Sarita <Hoyt.Sarita@epa.gov>; Mosby, Jackie <Mosby.Jackie@epa.gov>; Miller, Wynne <Miller.Wynne@epa.gov>

Subject: FW: FROM OMB: EO 12866 Interagency Review: EPA's Guidance for Plant Biostimulant Products: Label Claims Excluded or Regulated under FIFRA as Plant Regulator Claims (RIN 2070-ZA21) - Interagency Comments

Hi all,

I asked Danielle about Comment [A13], page 12, line 236 in the guidance document, which recommends soliciting comment on the different proposed definitions and if EPA should consider codifying a definition for PBS in a future rulemaking.

Alyssa had commented that it's unclear which proposed definitions (the farm bill or the EU definition) they are referring to. And it might be helpful to specify which proposed definitions. That clarification should also make it clear to the reader that EPA is not proposing a definition with this document.

Danielle responded that the proposed definitions were in reference to the Farm Bill and/or EU definition. The comment could also be tailored more towards whether the agency should consider codifying a definition for purposes under FIFRA, but the later might be better than adopting either the proposed definitions in the Farm Bill or EU.

I said that we were thinking about adding a sentence to the guidance document and the FR Notice along the lines of:

"EPA is seeking public comment on this draft. EPA also requests comment on whether the Agency should consider codifying a definition for plant biostimulants in a future rulemaking."

She is o.k. with the revised language.

-Melissa

From: Chun, Melissa

Sent: Tuesday, December 18, 2018 11:55 AM

To: Jones, Russell <Jones.Russell@epa.gov>; McNally, Robert <McNally.Robert@epa.gov>; Varco, Joseph <varco.joseph@epa.gov>; Ambrosino, Helene <Ambrosino.Helene@epa.gov>; Gsell, Alyssa <Gsell.Alyssa@epa.gov>; VanAkkeren, Brett <VanAkkeren.Brett@epa.gov>; Wyatt, TJ <Wyatt.TJ@epa.gov>; Hofmann, Angela <Hofmann.Angela@epa.gov>; Chumble, Prasad <Chumble.Prasad@epa.gov>; Smoot, Cameo <Smoot.Cameo@epa.gov>; Watkins, Stephen <watkins.stephen@epa.gov>; Hoyt, Sarita <Hoyt.Sarita@epa.gov>; Mosby, Jackie <Mosby.Jackie@epa.gov>; Miller, Wynne <Miller.Wynne@epa.gov>

Subject: FW: FROM OMB: EO 12866 Interagency Review: EPA's Guidance for Plant Biostimulant Products: Label Claims Excluded or Regulated under FIFRA as Plant Regulator Claims (RIN 2070-ZA21) - Interagency Comments

Hi all,

I talked with Danielle about the biostimulants guidance during our bi-weekly meeting this morning.

She mentioned that USDA had comments on the guidance document that they will send to her today. Danielle will get them to us as soon as she can.

With respect to the edits on lines 15-18, we can't use the word "are." As guidance, this document is not binding and we cannot use declarative language, such as "are." OMB will accept the language "may be," "generally are," or "would be." We could use the word "are" if we were codifying language in a rule. I've revised this section to use "generally are."

On page 6, line 115, I added the language that was brought up during staff meeting, i.e., Should we take public comment on whether EPA should consider developing a definition?

"EPA is seeking public comment on this draft. EPA also requests comment on the different proposed definitions and whether EPA should consider codifying a definition for plant biostimulants in a future rulemaking."

Please note that the call with DOJ will need to be scheduled the 1st week of January. DOJ indicated that they are available on January 3rd, 7th and 8th. Please let me know your availability (2 or more times if possible).

I'm attaching a revised version of the FR Notice.

Thanks!

-Melissa

From: Gsell, Alyssa

Sent: Monday, December 17, 2018 4:04 PM

To: Chun, Melissa <Chun.Melissa@epa.gov>; Jones, Russell <Jones.Russell@epa.gov>; McNally, Robert

<McNally.Robert@epa.gov>; Varco, Joseph <varco.joseph@epa.gov>; Ambrosino, Helene <Ambrosino.Helene@epa.gov>; VanAkkeren, Brett <VanAkkeren.Brett@epa.gov>; Wyatt, TJ <Wyatt.TJ@epa.gov>; Hofmann, Angela <Hofmann.Angela@epa.gov>; Chumble, Prasad <Chumble.Prasad@epa.gov>; Smoot, Cameo <Smoot.Cameo@epa.gov>; Watkins, Stephen <watkins.stephen@epa.gov>; Hoyt, Sarita <Hoyt.Sarita@epa.gov>; Mosby, Jackie <Mosby.Jackie@epa.gov>

Subject: RE: FROM OMB: EO 12866 Interagency Review: EPA's Guidance for Plant Biostimulant Products: Label Claims Excluded or Regulated under FIFRA as Plant Regulator Claims (RIN 2070-ZA21) - Interagency Comments

For the edits on lines 15-18, could we use "generally are" instead of "may be"? OGC understands that the examples are real life examples, where the claims have been determined to be (or not be) considered PBS. The term "generally are" may be an acceptable compromise between the original EPA language and the proposed OMB language.

Thanks.

Alyssa M. Gsell
US EPA Office of General Counsel
Phone: 202-564-7413
Fax: 202-564-5416

From: Chun, Melissa

Sent: Sunday, December 16, 2018 6:49 PM

To: Jones, Russell <Jones.Russell@epa.gov>; McNally, Robert <McNally.Robert@epa.gov>; Varco, Joseph <varco.joseph@epa.gov>; Ambrosino, Helene <Ambrosino.Helene@epa.gov>; Gsell, Alyssa <Gsell.Alyssa@epa.gov>; VanAkkeren, Brett <VanAkkeren.Brett@epa.gov>; Wyatt, TJ <Wyatt.TJ@epa.gov>; Hofmann, Angela <Hofmann.Angela@epa.gov>; Chumble, Prasad <Chumble.Prasad@epa.gov>; Smoot, Cameo <Smoot.Cameo@epa.gov>; Watkins, Stephen <watkins.stephen@epa.gov>; Hoyt, Sarita <Hoyt.Sarita@epa.gov>; Mosby, Jackie <Mosby.Jackie@epa.gov>

Subject: FW: FROM OMB: EO 12866 Interagency Review: EPA's Guidance for Plant Biostimulant Products: Label Claims Excluded or Regulated under FIFRA as Plant Regulator Claims (RIN 2070-ZA21) - Interagency Comments

Hi all,

Here's the mark-up for the FR Notice.

On page 1, lines 15-18, the language "may be" seems appropriate since we are using this guidance to help determine whether product label claims are plant regulator claims or not. Do we need to be more specific?

On page 4, lines 79-84, the revisions to streamline and clarify this section are o.k. I added a sentence from the guidance document that OMB provided on the uncertainty of costs and cost savings. Do we need more detail?

Please forward your comments to everyone on this e-mail.

Thanks!

-Melissa

From: Chun, Melissa

Sent: Friday, December 14, 2018 12:08 PM

To: Jones, Russell <Jones.Russell@epa.gov>; McNally, Robert <McNally.Robert@epa.gov>; Varco, Joseph <varco.joseph@epa.gov>; Ambrosino, Helene <Ambrosino.Helene@epa.gov>; Gsell, Alyssa <Gsell.Alyssa@epa.gov>; VanAkkeren, Brett <VanAkkeren.Brett@epa.gov>; Hofmann, Angela <Hofmann.Angela@epa.gov>; Chumble, Prasad <Chumble.Prasad@epa.gov>; Smoot, Cameo <Smoot.Cameo@epa.gov>; Watkins, Stephen <watkins.stephen@epa.gov>; Hoyt, Sarita <Hoyt.Sarita@epa.gov>; Mosby, Jackie <Mosby.Jackie@epa.gov>

Subject: FW: FROM OMB: EO 12866 Interagency Review: EPA's Guidance for Plant Biostimulant Products: Label Claims Excluded or Regulated under FIFRA as Plant Regulator Claims (RIN 2070-ZA21) - Interagency Comments

We walked through the comments, made assignments, and flagged one that will need to be raised to the DAA's.

Russell and Bob are responding to the comments on the guidance document and I'll work on the FR Notice with help from Alyssa on the "are" vs. "maybe" in the summary and TJ on the uncertainty of costs and cost savings.

We'll send the mark-ups around on Monday for folks to comment on.

This is the comment that was flagged in the Summary for the guidance document:

Summary: This document is intended to provide guidance on identifying product label claims, including for plant biostimulants, that are considered to be pesticidal in nature (*i.e.* plant regulator claims), thereby subjecting the products to regulation under FIFRA as pesticides. As guidance, this document is not binding on the Agency or any outside parties, and the Agency may depart from it where circumstances warrant and without prior notice. EPA is seeking public comment on this draft.

OMB commented: Recommend soliciting comment on the different proposed definitions and if EPA should consider codifying a definition for PBS in a future rulemaking.

After we've agreed on the responses/edits, the documents will go to Rick and the DAA's on Tuesday for their approval, before sending the responses to OMB.

Please note that there might be a second set of comments from USDA next Tuesday.

Thanks everyone!

-Melissa

Melissa L Chun | US EPA | Regulatory and Information Coordination Staff | Office of Chemical Safety and Pollution Prevention | 1200 Pennsylvania Ave., NW | William Jefferson Clinton Building East Room 3425E, Mail Code 7101M | Washington DC 20460 | phone: (202) 564-1605

From: Chun, Melissa

Sent: Friday, December 14, 2018 9:35 AM

To: Jones, Russell <Jones.Russell@epa.gov>; McNally, Robert <McNally.Robert@epa.gov>; Varco, Joseph <varco.joseph@epa.gov>; Ambrosino, Helene <Ambrosino.Helene@epa.gov>; Gsell, Alyssa <Gsell.Alyssa@epa.gov>; VanAkkeren, Brett <VanAkkeren.Brett@epa.gov>; Hofmann, Angela

<Hofmann.Angela@epa.gov>; Chumble, Prasad <Chumble.Prasad@epa.gov>; Smoot, Cameo
<Smoot.Cameo@epa.gov>; Watkins, Stephen <watkins.stephen@epa.gov>; Hoyt, Sarita
<Hoyt.Sarita@epa.gov>

Subject: FROM OMB: EO 12866 Interagency Review: EPA's Guidance for Plant Biostimulant Products:
Label Claims Excluded or Regulated under FIFRA as Plant Regulator Claims (RIN 2070-ZA21) - Interagency
Comments

Hi all,

Here are the interagency reviewer comments from OMB.

We go through them at 11 am.

-Melissa

Melissa L Chun | US EPA | Regulatory and Information Coordination Staff | Office of Chemical Safety
and Pollution Prevention | 1200 Pennsylvania Ave., NW | William Jefferson Clinton Building East Room
3425E, Mail Code 7101M | Washington DC 20460 | phone: (202) 564-1605

From: Jones, Danielle Y. EOP/OMB <Danielle_Y_Jones@omb.eop.gov>

Sent: Friday, December 14, 2018 9:29 AM

To: Chun, Melissa <Chun.Melissa@epa.gov>

Cc: Hofmann, Angela <Hofmann.Angela@epa.gov>; VanAkkeren, Brett <VanAkkeren.Brett@epa.gov>

Subject: EO 12866 Interagency Review: EPA's Guidance for Plant Biostimulant Products: Label Claims
Excluded or Regulated under FIFRA as Plant Regulator Claims (RIN 2070-ZA21)

Good morning Melissa,

Please find attached the interagency reviewers comments on the Guidance for Plant Biostimulant
Products: Label Claims Excluded or Regulated under FIFRA as Plant Regulator Claims (RIN 2070-ZA21).

Please let me know if you have any questions.

Best,
Danielle

Danielle Y. Jones
Senior Policy Analyst
Office of Management and Budget
Phone: (202) 395-1741 | djones@omb.eop.gov

<EO 12866 rin2070-ZA21_EO12866_PBSGuidance-Draft_FRdocument_2018-10-31_mc_2018-
12-14_rev_2018-12-18_v2 tjw.docx>

<EO 12866 rin2070-ZA21_EO12866review_PBSGuidance-Draft_2018-11-011_rev_mc_2019-
01-29 tjw.docx>